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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,419	07/27/2001	William P. Kelleher	CSLL-624	8855

7590

10/06/2003

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,419

Applicant(s)

KELLEHER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,8. 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 12 March 2002 and 16 Oct. 2002 have been considered and made of record.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claims 14 and 15, it is recited that the film of conjugated polymer molecules are inorganic molecules (See claim 14) wherein the inorganic molecules are TNT (See claim 15). These claim limitations do not have antecedent basis in the instant specification because these limitations are associated with the sample fluid rather than the coating in the specification (See page 12, lines 16-23). That is, according to the instant specification, TNT is the chemical microorganism that is detected, not a molecule of the film on the internal surface of the photonic band gap structure.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With respect to claim 15, it is not clear how TNT can be identified as an inorganic molecule when it includes organic molecules. Clarification and/or correction is requested.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1, 3-9, 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903).

The reference of Grey et al. discloses a fluorescence detection system which includes a fiber optic (18) which includes a surface coated with a plurality of molecules (See all of column 3). A sample fluid having a plurality of microorganisms (TNT) (See applicants' definition of microorganism on page 12, lines 16-23, of the instant specification) dispersed therein is contacted with the coated molecules. The device includes an optical source for generating excitation light and an optical detector for detecting a resultant fluorescence signal (See column 6, line 60, to column 7, line 2).

The above claims differ by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region.

The reference of Broeng et al. discloses that it is known in the art to employ photonic band gap optical fibers in sensor applications because of the advantages associated with these structures over conventional fiber optical waveguides (See pages 1-7). The reference discloses providing a void in the fiber and means for providing a sample gas or liquid in the void (See pages 19-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a photonic band gap structure in place of the conventional cladded optical fiber of the primary reference for the known and expected advantages associated with the photonic band gap structure as discussed by the reference of Broeng et al.

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With respect to claims 3, 14 and 15, the reference of Grey et al. discloses the use of a conjugated polymer structure for interacting with the microorganism (TNT). Note, the interaction of the TNT molecules with the PAH coating is considered to meet these claim limitations.

With respect to the claimed wavelengths and/or dimensions of claims 4, 5, 7, 8, 12, 13, 18 and 20, it would have been obvious to one of ordinary skill in the art to determine the optimum construction of the device based merely on the microorganism and molecule employed while maintaining the efficiency of the detection system.

With respect to claim 6, the coating material includes a fluorescing agent, PAH.

With respect to claims 9 and 11, while the references of Grey et al. and Broeng et al. disclose the use of excitation light and light detection, the references are silent as to specific light source and detector. However, it would have been obvious to one of ordinary skill in the art to determine which light source to employ and detector based merely on the specifics of the detection to be performed. Note both lasers and photomultiplier tubes are notoriously well known in the art of chemical optical detection.

With respect to claims 16 and 17, the device is capable of being used with either a gas or liquid sample (See page 20 of Broeng et al.).

With respect to claim 19, the structure of Broeng et al. is considered a photonic band gap fiber.

9. Claims 1-5, 7-13, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903).

The reference of Ligler et al. discloses a fluorescence detection system that can be which includes a fiber optic (10) which includes a surface coated with a plurality of molecules (See Figure 2). A sample fluid having a plurality of microorganisms (30) dispersed therein is contacted with the coated molecules. The device includes an optical source for generating excitation light and an optical detector for detecting a resultant fluorescence signal (See Figure 2 and Example 2).

The above claims differ by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region.

The reference of Broeng et al. discloses that it is known in the art to employ photonic band gap optical fibers in sensor applications because of the advantages associated with these structures over conventional fiber optical waveguides (See pages 1-7). The reference discloses providing a void in the fiber and means for providing a sample gas or liquid in the void (See pages 19-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a photonic band gap structure in place of the conventional cladded optical fiber of the primary reference for the known and expected advantages associated with the photonic band gap structure as discussed by the reference of Broeng et al.

With respect to claim 2, the microorganisms bind with the molecules on the surface.

With respect to claim 3, the binding molecules are conjugated onto the surface of the optical structure (See Example 2).

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With respect to the claimed wavelengths and/or dimensions of claims 4, 5, 7, 8, 12, 13, 18 and 20, it would have been obvious to one of ordinary skill in the art to determine the optimum construction of the device based merely on the microorganism and molecule employed while maintaining the efficiency of the detection system.

With respect to claim 9, the reference of Ligler et al. discloses the use of a laser (See Example 2).

With respect to claim 10, the detected microorganisms are bacteria (See Example 2).

With respect to claim 11, while the reference of Ligler et al. discloses the use of a photodiode, it would have been obvious to one of ordinary skill in the art to employ alternative detectors based merely on the specifics of the detection to be performed. Note photomultiplier tubes are notoriously well known in the art of chemical optical detection.

With respect to claims 16 and 17, the device is capable of being used with either a gas or liquid sample (See page 20 of Broeng et al.).

With respect to claim 19, the structure of Broeng et al. is considered a photonic band gap fiber.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894).

The combination of the references of Grey et al. and Broeng et al. has been discussed above.

Claim 21 differs by reciting that the detection system is manufactured as an array of

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fibers.

Both the references of Walt et al. and Pinkel et al. disclose that it is well known in the art to provide an array of optical fiber structures when performing a chemical detection so as to perform multiple assays (See the abstracts of both references).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to employ an array of band gap fibers when employing the device to detect more than one kind of analyte. Each void would include a different molecule and would allow a single sample to be analyzed for a plurality of different analytes.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894).

The combination of the references of Ligler et al. and Broeng et al. has been discussed above.

Claim 21 differs by reciting that the detection system is manufactured as an array of fibers.

Both the references of Walt et al. and Pinkel et al. disclose that it is well known in the art to provide an array of optical fiber structures when performing a chemical detection so as to perform multiple assays (See the abstracts of both references).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to employ an array of band gap fibers when employing the device to detect more than one kind of analyte. Each void would include a different molecule and would allow a single sample

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to be analyzed for a plurality of different analytes.

Conclusion

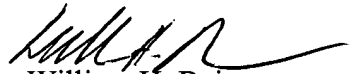
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Hirschfeld (US 4,447,546) is cited as prior art that pertains to a fluorescent immunoassay device that includes a sample-retaining chamber.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB